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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,194	07/23/2003	Thomas P. Coen	2024729-7014395001	1248

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Bingham McCutchen LLP
Suite 1800
Three Embarcadero Center
San Francisco, CA 94111-4067

EXAMINER

FLANAGAN, BEVERLY MEINDL

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/625,194	Applicant(s) COEN ET AL.	
	Examiner Beverly M. Flanagan	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,38,42,46,48-52,54 and 55 is/are rejected.
- 7) ☒ Claim(s) 37,39-41,43-45,47 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.


Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.


BEVERLY M. FLANAGAN
PRIMARY EXAMINER

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed October 6, 2003 been made of record and the references cited therein have been considered by the examiner.

Preliminary Amendment

The preliminary amendment filed July 23, 2003 has been entered and made of record. Accordingly, the status of the claims is as follows: Claims 1-35 are canceled; Claims 36-55 are newly added.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 38, 42, 48-51, 54 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Hluchy et al. (U.S. Patent No. 5,688,222).

In regard to claims 36, 38, 42, 48-51, 54 and 55, Hluchy et al. teach an instrument 10 comprised of an inner sheath 11 that houses endoscope optics 12 within an inner lumen where inner sheath 11 is enclosed by an outer sheath 16 (see Figure 1). Figure 1 shows that the sheaths 11 and 16 have open distal ends. A hole 20 is provided in inner sheath 11 that is in fluid communication with the inner lumen of the

instrument and apertures 18 in outer sheath 16 (see Figure1). As broadly as claimed, the apertures 18 are configured to perfuse fluid in a substantially distal direction. It is the examiner's opinion that the instrument 10 of Hluchy et al. is capable of use as an intravascular sheath.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46 and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Hluchy et al. (U.S. Patent No. 5,688,222) in view of Muller et al. (U.S. Patent No. 5,807,240).

In regard to claims 46 and 52, Hluchy et al. are silent as to a valve mounted on the proximal end of instrument 10 for controlling the flow of fluid (but indicate that the flow can be suppressed by an appropriate control – see col. 3, lines 36-38 of Hluchy et al.). However, Muller et al. Disclose a similar instrument having a sheath 30 with apertures 38 where a fluid inlet 44 has a valve for controlling fluid flow (see Figure 1). Muller et al. thus demonstrate that the use of valves to control fluid flow in a sheath-type instrument is well known in the art. Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the instrument 10

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of Hluchy et al. with a valve mounted on the proximal end of the instrument 10 to control the fluid flow.

Allowable Subject Matter

Claims 37, 39-41, 43-45, 47 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Beverly M. Flanagan whose telephone number is (571) 272-4766. The examiner can normally be reached on Mondays, Wednesdays and Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Beverly M. Flanagan
Primary Examiner
Art Unit 3739
